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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,264	02/16/2001	William H. Fleming	6122-54472	8684

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EXAMINER

GRAYSON, ANGELA J

ART UNIT PAPER NUMBER

3765

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,264

Applicant(s)

FLEMING, WILLIAM H.

Examiner

Angela J. Grayson, Esq.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☒ Claim(s) 23-43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 23-43 been renumbered 26-46.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 15 recites the limitation "the therapeutic" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4; 7-16; 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,527,534 to Myhling.

As to claims 1, Myhling discloses an interlabial delivery device comprising a delivery material (col. 1 lines 10-15) retained between the labia and carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent (col. 1 lines 17-22).

As to claim 2, Myhling discloses an interlabial delivery device wherein the delivery material is a pad configured to be retained between the labia of the subject. (col. 1 lines 10-15).

As to claim 3, Myhling discloses an interlabial delivery device wherein the pad is highly absorbent non-swellable material. (col. 8 lines 27-29).

As to claim 4, Myhling discloses an interlabial delivery device wherein the pad has a uniform cross-section along its entire length or is tapered along its length. (Figure 2).

As to claims 7-9, Myhling discloses an interlabial delivery device wherein the delivery material includes an agent for absorbing odors, diagnostic, therapeutic. (See Table 1 col. 15).

As to claim 10, Myhling discloses an interlabial delivery device wherein the delivery device comprises an intravaginal portion and an extravaginal portion, and the intravaginal portion carries the agent to be delivered. (Figure 1 members 2 and 6).

As to claims 11-14, Myhling discloses an interlabial delivery device wherein the agent is an antibiotic, or antifungal agent, is a hormone, is a transdermal agent, or agent is a drug in a unit dosage form. (Table 1 col. 15; Abstract).

As to claim 15, Myhling discloses a method of treating a disease comprising positioning a device configured to be retained between labia of a subject in an interlabial space of a subject in need of the therapeutic agent to treat the disease, wherein the device is a pad which carries a therapeutically or diagnostically effective amount of an active agent, or the agent has already been applied to the labia or administered intra-vaginally prior to placing the pad in the interlabial space. (col. 1 lines 10-22).

As to claim 16, Myhling discloses a method wherein the device is placed substantially completely external to a vaginal orifice. (Figure 4 member 1).

As to claims 20 and 21, Myhling discloses a method of locally delivering the agent to the peri-labial area; wherein the method is a method of systemically delivering the agent. (col. 4 lines 51-56).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5 and 6; 17-19; 22-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myhling in view of US Patent No. 3,983,873 to Hirschman.

As to claims 5 and 6, Myhling discloses a delivery device but fails to disclose wherein the pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion

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and wherein the minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space; wherein the minor and major portion of the pad have an elliptical cross-section with a major axis, wherein the major axis of the minor portion is less than the major axis of the major portion. However, Hirschman makes such a disclosure (Hirschman See Figures 1-14; Figure 1 respectively). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Myhling to include the design of Hirschman since Myhling suggests the shape of the delivery system is determined by choice (Myhling col. 8 lines 45-57).

As to claims 17, 18, & 19, Myhling discloses a method comprises inserting the pad into an interlabial space to push the labia apart as the leading edge of the pad is inserted between the labia (col. 4 lines 51-56), but fails to disclose wherein the pad has a tapered leading edge; wherein the tapered leading edge is positioned against the vaginal orifice, and a remainder of the pad has a width which is wider than a normal anatomic interlabial space, such that the remainder of the pad is frictionally engaged and retained by opposing labia; wherein the pad is elongated; . However, Hirschman makes such a disclosure (Figures 1-6, 8-14; Figure 20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Myhling with the design of Hirschman since Myhling suggests the shape of the delivery system is determined by choice (Myhling col. 8 lines 45-57) and Hirschman suggests the configurations facilitates the secure containment in the interlabial space (Hirschman col. 1 lines 25-26).

As to claims 22 and 25, Myhling in view of Hirschman discloses a method for administering a drug, comprising inserting a pad impregnated with the drug into the subject's interlabial space (Myhling col. 4 lines 51-56), positioning the pad adjacent to the subject's external vaginal orifice (Myhling Figure 4), wherein the pad is devoid of corners and flat surfaces intermediate its ends (Myhling Figure 2), the pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area of the major portion, wherein both the minor and major portion are curvilinear in cross-section, and wherein both the minor and major portion are curvilinear in cross-section, and wherein the minor portion facilitates insertion between the subject's labia and retention in the interlabial space (Hirschman See Figures 1-14; Figure 1 respectively).

As to claim 23, Myhling in view of Hirschman discloses a method wherein the pad is elongated and has a uniform cross-section along its entire length, or is tapered along its length. (Hirschman Figures 1-14).

As to claim 24, Myhling in view of Hirschman discloses a method wherein the pad is elongated, and when placed in the interlabial space, extends external to the vaginal orifice. (Hirschman Figures 1-14; col. 1 lines 25-26).

As to claim 25, Myhling in view of Hirschman discloses a method wherein the pad carries a therapeutically effective amount of medicinal agent, and positioning the pad comprises administering the medicinal agent to the subject. (Myhling col. 4 lines 45-56).

As to claim 26, Myhling in view of Hirschman discloses a method wherein the medicinal agent is an anti-fungal agent or a hormone. (Myhling Table 1 col. 15).

As to claim 27, Myhling in view of Hirschman discloses a method wherein the hormone is estrogen or testosterone. (Myhling col. 20 lines 9-10).

As to claim 28, Myhling in view of Hirschman discloses a method for treating a symptom comprising positioning an interlabial elongated absorbent pad such that the pad is retained between the labia external to the subject's vaginal orifice (Myhling Figure 4), wherein the pad comprises a longitudinally extending major portion and a longitudinally extending minor portion (Hirschman Figures 1-14)

As to claim 28, Myhling in view of Hirschman discloses a method for treating a symptom comprising positioning an interlabial elongated absorbent pad such that the pad is retained between the labia external to the subject's vaginal orifice (Myhling Figure 4), wherein the pad comprises a longitudinally extending major portion and a longitudinally extending minor portion (Hirschman Figures 1-14)

As to claim 29, Myhling in view of Hirschman discloses a method wherein the minor and major portions of the pad have a length greater than their width, and the shape of the pad substantially conforms to the interlabial space in which the pad is retained. (Hirschman Figures 1-14; col. 1 lines 20-31).

As to claim 30, Myhling in view of Hirschman discloses a method wherein the pad is held between the labia without adhesive or attachment to a supporting garment. (Hirschman Figure 20).

As to claims 31, 32, and 36, Myhling in view of Hirschman discloses a method wherein the major portion of the pad has longitudinally extending opposed substantially parallel face portions; wherein the minor portions of the pad has longitudinally extending, opposed substantially parallel face portions. (Hirschman Figures 1-14).

As to claims 33, 34, 35, and 37, Myhling in view of Hirschman discloses a method wherein the opposed flat face portions of the pad are substantially parallel; wherein the opposed flat face portions of the pad are substantially convergent. (Hirschman Figures 1-14).

As to claim 38, Myhling in view of Hirschman discloses a method wherein the minor and major portions of the pad have a shoulder shaped junction. (Hirschman Figures 2-6, 8, 11, 12).

As to claim 39, Myhling in view of Hirschman discloses a method wherein the pad carries a therapeutically effective amount of a medicinal agent, and positioning the pad comprises administering the medicinal agent to the subject to relieve the symptom. (Myhling Abstract).

As to claim 40, Myhling in view of Hirschman discloses a method wherein the medicinal agent is an antimicrobial or a hormone. (Myhling Table 1 col. 15; col. 20, lines 9-10).

As to claim 41, 42, 43, and 44, Myhling in view of Hirschman discloses a method, wherein the pad includes a cavity in which a medicinal agent is placed prior to positioning the pad; wherein the cavity is compressed between the labia when the pad is positioned; wherein the cavity communicates with an exterior surface of the pad;

wherein the cavity is a recess in an exterior surface of the pad. (Myhling col. 12 lines 13-55).

As to claim 45, Myhling in view of Hirschman discloses a method wherein the pad is elongated, and the cavity extends longitudinally along the pad. (Hirschman Figures 1-14).

As to claim 46, Myhling in view of Hirschman discloses a method wherein the method further comprises applying medication intravaginally or perilabially prior to or simultaneously with positioning the pad. (Myhling col. 4 lines 40-49).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela J. Grayson, Esq. whose telephone number is 703-305-1806. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J. Calvert can be reached on 703-305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

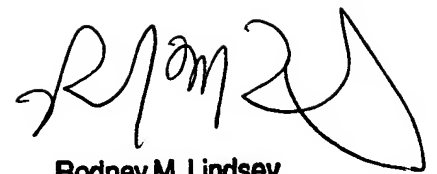
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

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Angela J. Grayson, Esq. *AG*
February 19, 2003

A handwritten signature in black ink, appearing to read 'R. M. Lindsey', with a large, stylized flourish at the end.

Rodney M. Lindsey
Primary Examiner